

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Marcus A. Horwitz

Group Art Unit 186

LEGIONELLOSIS VACCINES  
AND METHODS FOR THEIR  
PRODUCTION

Examiner: Mohamed, A.

Serial No. 232,664

Filed: August 16, 1988

Docket No.: 70-155

DECLARATION UNDER RULE 132

Honorable Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

I, Marcus A. Horwitz, M.D., declare and state that:

1. I am the inventor in the above-identified patent application.

2. I received my M. D. Degree from Columbia University College of Physicians and Surgeons, New York, New York in June of 1972 and am currently Professor of Medicine and of Microbiology and Immunology, Chief, Division of Infectious Diseases, Department of Medicine, UCLA School of Medicine, Center for the Health Sciences at Los Angeles, California. A copy of my current curriculum Vitae

detailing my Education, Internship and Residency, Public Health Service Positions, Clinical Fellowships, Research Fellowships, Faculty Positions, Certifications, Affiliations, Honors and Awards, Scientific and Editorial Boards and Study Sections, Publications, Abstracts, and Presentations at National or International Meetings was previously made of record as Exhibit 1 to my earlier Declaration Under Rule 132 filed June 4, 1990. As indicated in my Curriculum Vitae, I have extensive experience in the fields of Microbiology, Immunology and Infectious Diseases.

3. I have reviewed the Official Action dated August 9, 1991, wherein the Examiner requested that I provide my actual data showing that Mycobacterium tuberculosis extracellular proteins induce cell-mediated immunity in humans. Accordingly, I have tabulated this data in the attached Tables I and II and plotted the data from both tables in the attached Figure 1. The protocol for the generation of this data is as follows.

4. To determine if M. tuberculosis extracellular proteins induce cell-mediated immunity in humans, we studied the proliferative responses to M. tuberculosis extracellular proteins of lymphocytes from persons previously infected with M. tuberculosis, as evidenced by a positive skin test response to purified protein derivative (PPD) of M. tuberculosis (PPD+ persons) and lymphocytes from persons not previously infected with M.

tuberculosis, as evidenced by a negative skin test response to PPD (PPD- persons).

5. In a standard lymphocyte proliferation assay, lymphocytes from PPD+ persons responded strongly to Extracellular Proteins of M. tuberculosis including the Major Extracellular Protein. A representative experiment is shown in Table I, Experiment 1 in which there was a peak stimulation index of 29.9 in response to Extracellular Proteins and a peak stimulation index of 38.6 in response to the Major Extracellular Protein.

6. In contrast, lymphocytes from PPD- persons responded weakly, if at all, to M. tuberculosis extracellular proteins. A representative experiment is shown in Table 1, Experiment 2 in which there was a peak stimulation index of only 5.0 (day 4) in response to Extracellular Proteins and 4.5 (day 2) in response to the Major Extracellular Protein.

7. Cumulative results from 8 independent experiments on 3 PPD+ and 3 PPD- persons are tabulated in Table II. Peak stimulation indices for lymphocytes from PPD+ persons in response to M. tuberculosis Extracellular Proteins averaged  $47.6 \pm 12.9$  (Mean  $\pm$  S.E.), whereas peak stimulation indices for lymphocytes from PPD- persons in response to M. tuberculosis extracellular proteins averaged  $7.5 \pm 4.5$  (Mean  $\pm$  S.E.).

8. Thus, the mean response of lymphocytes from PPD+ persons

was over 6-fold that of lymphocytes from PPD- persons to M. tuberculosis extracellular proteins. Peak stimulation indices for lymphocytes from PPD+ persons in response to M. tuberculosis Major Extracellular Protein averaged  $30.2 \pm 5.8$  (Mean + S.E.), whereas peak stimulation indices for lymphocytes from PPD- persons in response to M. tuberculosis Major Extracellular Protein averaged  $2.7 \pm 0.9$  (Mean + S.E.). The mean response of lymphocytes from PPD+ persons was over 11-fold that of lymphocytes from PPD- persons to M. tuberculosis Major Extracellular Protein.

9. The striking differences in the magnitude of the proliferative responses to M. tuberculosis Extracellular Proteins of lymphocytes from PPD+ and PPD- persons can be further appreciated from Figure 1 in which data from Table II is plotted. These data clearly demonstrate that persons infected with M. tuberculosis develop a very strong cell-mediated immune response to M. tuberculosis extracellular proteins.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize

Marcus A. Horwitz, Serial No. 232,664

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the validity of the above-identified patent application or any patent issuing thereon.

Date: 10/30/91

Marcus A. Horwitz  
Marcus A. Horwitz, M.D.

TABLE I

TWO REPRESENTATIVE EXPERIMENTS DEMONSTRATING THAT PERIPHERAL BLOOD LYMPHOCYTES FROM PPD+ PERSONS BUT NOT PPD- PERSONS PROLIFERATE MARKEDLY TO EXTRACELLULAR PROTEINS OF M. TUBERCULOSIS AND THE MAJOR EXTRACELLULAR PROTEIN

I. Lymphocyte Proliferation to Extracellular Proteins of M. tuberculosis:

| Expt | Patient | PPD | Status | Day | Stimulation Indices* in Response to Indicated Amount of Extracellular Protein(ug/ml) |      |      |      |
|------|---------|-----|--------|-----|--|------|------|------|
|      |         |     |        |     | 0.01   | 0.1  | 1.0  | 10.0 |
| 1    | DG      | +   | +      | 4   | 2.4  | 15.7 | 27.3 | 29.9 |
| 2    | DK      | -   | -      | 2   | 0.2  | 0.6  | 1.4  | 1.6  |
|      |         |     |        | 4   | 0.5  | 1.1  | 3.4  | 5.0  |

II. Lymphocyte Proliferation to Major Extracellular Protein of M. tuberculosis:

| Expt | Patient | PPD | Status | Day | Stimulation Indices* in Response to Indicated Amount of Major Extracellular Protein(ug/ml) |      |      |      |
|------|---------|-----|--------|-----|--|------|------|------|
|      |         |     |        |     | 0.01   | 0.1  | 1.0  | 10.0 |
| 1    | DG      | +   | +      | 4   | 3.9  | 12.7 | 38.6 | 35.2 |
| 2    | DK      | -   | -      | 2   | 0.4  | 1.9  | 4.5  | 3.8  |
|      |         |     |        | 4   | 1.0  | 2.0  | 3.9  | 1.1  |

Peripheral blood lymphocytes were purified by conventional methodology from a person who was PPD+ (Experiment 1) and a person who was PPD- (Experiment 2). The lymphocytes were incubated in microtest wells at 37°C in 5% CO<sub>2</sub>- 95% air for 2 or 4 days in tissue culture medium containing autologous serum, polymixin B, and 0, 0.01, 0.1, 1.0, or 10 ug/ml M. tuberculosis extracellular proteins or M. tuberculosis Major Extracellular Protein. The lymphocytes were then assayed for their capacity to incorporate <sup>3</sup>H-thymidine, and Stimulation Indices were calculated.

(mean <sup>3</sup>H-thymidine incorporation of lymphocytes incubated with antigen)

\*Stimulation Index=-----

(mean <sup>3</sup>H-thymidine incorporation of lymphocytes incubated without antigen)

Table II

PERIPHERAL BLOOD LYMPHOCYTES FROM PPD+ BUT NOT PPD- PERSONS  
PROLIFERATE MARKEDLY IN RESPONSE M. TUBERCULOSIS  
EXTRACELLULAR PROTEINS

I. Lymphocyte Proliferation to Extracellular Proteins  
of M. tuberculosis

| PPD+ Persons |              | PPD- Persons |              |
|--------------|--------------|--------------|--------------|
| Expt.        | Peak<br>SI * | Expt.        | Peak<br>SI * |
| B            | 24.5         | F            | 5.0          |
| C            | 29.9         | G            | 16.3         |
| D            | 55.0         | H            | 1.1          |
| E            | 80.9         |              |              |

Mean+SE: 47.6+12.9 7.5+4.5

II. Lymphocyte Proliferation to Major Extracellular Protein  
of M. tuberculosis

| PPD+ Persons |              | PPD- Persons |              |
|--------------|--------------|--------------|--------------|
| Expt.        | Peak<br>SI * | Expt.        | Peak<br>SI * |
| A            | 19.2         | F            | 4.5          |
| B            | 18.1         | G            | 2.2          |
| C            | 38.6         | H            | 1.4          |
| D            | 48.3         |              |              |
| E            | 26.7         |              |              |

Mean+SE: 30.2+5.8 2.7+0.9

Peripheral blood lymphocytes were purified by conventional methodology from 3 PPD+ and 3 PPD- persons and assayed in 8 independent experiments. The lymphocytes were incubated in microtest wells at 37°C in 5% CO<sub>2</sub> - 95% air for 2-4 days in tissue culture medium containing autologous serum, polymixin B, and 0, 0.01, 0.1, 1.0, or 10.0 ug/ml M. tuberculosis Extracellular Proteins or M. tuberculosis Major Extracellular Protein. The lymphocytes were assayed for their capacity to incorporate <sup>3</sup>H-thymidine, and Stimulation Indices were calculated. Values are the peak Stimulation Index for each experiment.

(mean <sup>3</sup>H- thymidine incorporation to  
lymphocytes incubated with antigen

\*Stimulation Index=-----

(mean <sup>3</sup>H-thymidine incorporation of  
lymphocytes incubated without antigen

135

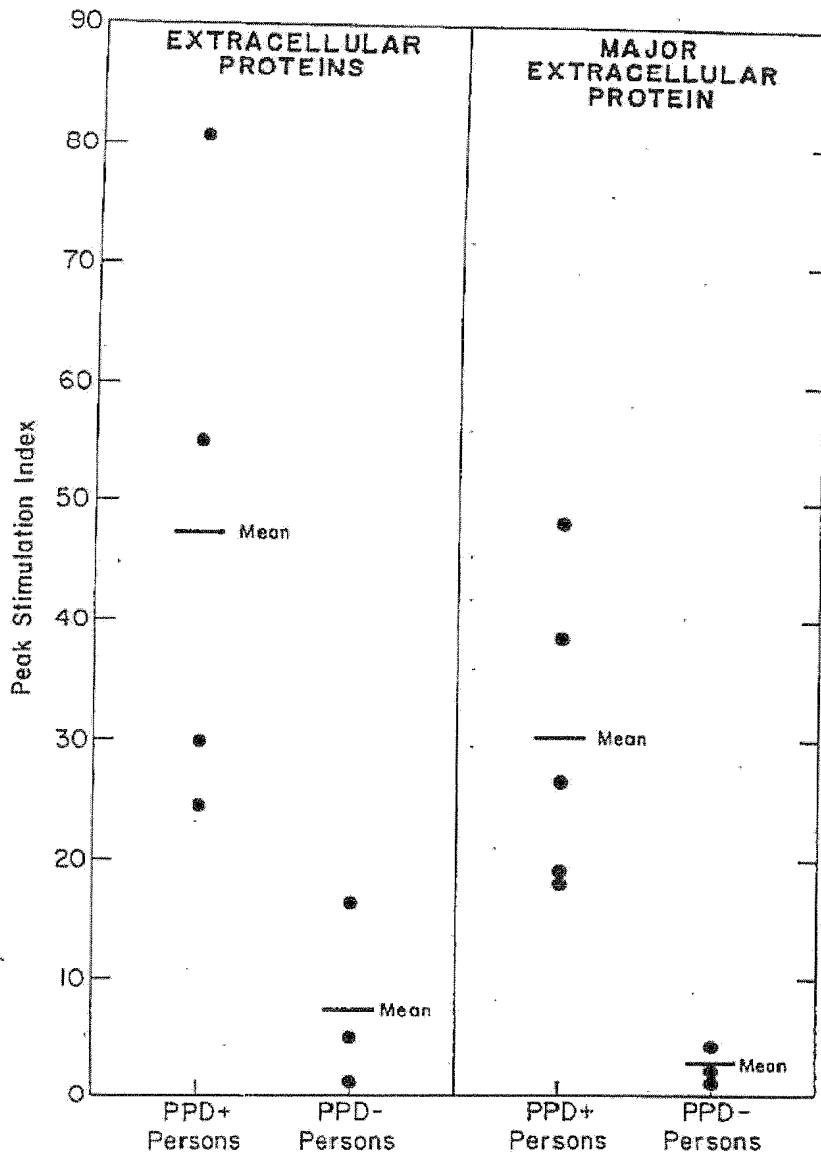


Figure 1. Peripheral blood lymphocytes from PPD+ but not PPD- persons proliferate markedly in response to M. tuberculosis Extracellular Proteins. Peak stimulation indices (data from Table II) of PPD+ and PPD- persons in response to Extracellular Proteins of M. tuberculosis or the Major Extracellular Protein of M. tuberculosis (right) are graphed.

## CURRICULUM VITAE

### Peter Andersen

2006 - Honorary Professor, The Royal Veterinary and Agricultural University, Department of Veterinary Pathobiology

2002- Vice President, Vaccine R & D, Director, Department of Infectious Disease Immunology

1997- 2002 Head of Department of TB Immunology

1996 D.Sc., Copenhagen University

1994 Head of the Tuberculosis Research Unit at Statens Serum Institut

1993: Position as senior scientist at the Bacterial Vaccine Department, Statens Serum Institut

1991-1993 Co-ordinator of the WHO collaborative research project: "The search for antigens of immunological relevance from *M. tuberculosis*"

1991-1992 Recipient of a fellowship from the Danish Association against Lung Diseases

1989-1991 Postgraduate scholarships from the Royal Veterinary and Agricultural University

1989 Scholarships at the Laboratory of Cellular Physiology, Rockefeller University, New York (Dr. Kaplan)

1988-1989 Research fellow at the Vaccine Department, Statens Serum Institut

1988 DVM from the Royal Veterinary and Agricultural University

1986-1987 Scholarships at the Marine Laboratory, Aberdeen, Scotland (Dr. Ellis) and the Marine Laboratory, Hokkaido, Japan (Dr. Sakai)

Peter Andersen, DVM, D.Sc, born 7 December 1961. As Vice President of Vaccine Research and Development at Statens Serum Institut, as well as co-ordinator of a number of International Research Grants, he has had extensive experience in assembling and directing multi-disciplinary research teams. Prof. Andersen's research has been focused on the identification and characterisation of antigens, immune mechanisms and vaccine delivery systems that mediate protection against important pathogens such as *Mycobacterium tuberculosis* and *Clamydia trachomatis*. In his current position, Prof. Andersen is responsible for the overall coordination of vaccine research and development at the SSI, covering activities from early research and to clinical development with more than 80 employees. This program currently has 2 different TB a novel liposomal adjuvant formulation and a new TB skintest under clinical testing and a number of experimental vaccines in the late preclinical stage. In collaboration with industrial partners the SSI antigen discovery programmes has furthermore resulted in three commercially available tests for TB diagnosis.

Dr. Andersen has served on a number of committees to advise and co-ordinate strategies for vaccine and diagnostic development. He has been organising and chairing several

at scientific meetings in the last eight years. Dr. Andersen is the inventor of more than 20 patent families and has published 200 papers within the field of infection, immunity and vaccine research in peer-reviewed journals.

**Scientific committees:**

- Steering Committee for TBVI "Tuberculosis Vaccine Initiative ", (2007-)
- Organizing Committee for The First Global Symposium on Interferon- $\gamma$  Assays "Rethinking the natural history and epidemiology of tuberculosis infection" (2006-7)
- Steering Committee for MUVAPRED "Mucosal Vaccines for Poverty Related Diseases" (2005- )
- Head of SSI-Centre of Vaccinology (2004- )
- Steering Committee for TBVAC "An integrated project for the design and testing of vaccine candidates against tuberculosis: identification, development and clinical studies". (2004- )
- Technical Advisory Group for the Foundation for Innovative New Diagnostics (FIND) (2004)
- Steering Committee for WHO's Initiative for Vaccine Research (IVR) (2004- )
- Member of Advisory Group for the NIH, NIAID Contract N01 AI-75320, "TB Research Materials and Vaccine Testing" (2002- )
- Section Editor for the journal Tuberculosis (2002- )
- Steering Committee for TB VACCINES FOR THE WORLD CONFERENCE - TBV (2003, 2006 and 2008)
- Steering Committee for WHO's Tropical Disease Research (TDR) (2001- )
- Steering group for WHO's Initiative for Vaccine Research (IVR) (2001- )
- High-Level Scientific Conferences Panel, European Commission (2001)
- Chair on Global Forum on TB Vaccines Research and Development, WHO (2001)
- Member of the management team for the European TB Vaccine Cluster (2000-2004)
- Member of the editorial board of Infection and Immunity (1995-1999)
- WHO adviser on TB Vaccine development (Immyc) (1993-1998)
- Chair of the meeting on TB vaccines organised by the International Union against TB and Lung Diseases (IUATLD) (1998)
- Organising committee of the scientific meeting "Cellular mechanism and molecules in Infection and Immunity" (1999 + 2002)
- Chairman of the WHO organised animal model task force for the evaluation of experimental tuberculosis vaccines (1998)
- Organising committee of The International Symposium on Tuberculosis Vaccine Development and Evaluation, San Francisco (1998)
- EU cost/STD initiated expert panel on vaccines against TB (1996)
- Committee member of The Elsinore Meeting on Infection Immunity (1993- )

**Prizes and awards:**

|      |  |
|------|--|
| 2006 | Honorary Professor, The Royal Veterinary and Agricultural University, Department of Veterinary Pathobiology            |
| 2005 | Thomson Scientific's distinction as the most quoted Danish scientist over the last 15 years in the field of Immunology |
| 2004 | Professor, dr.med. Fritz Kaufmann Memorial Fund  |
| 1999 | Thorvald Madsen Research Fund in recognition of an outstanding research achievement                                    |

**Patents:**

- New Fusion proteins (PCT/DK2006/000356)
- "Subdominant epitopes" PA 2006 00861
- "CFP7 and homologues thereof" (Continuation in part, Plougmann, Vingtoft & Partners ref. No. 20486 US 04)
- "A new specific epitope based immunological diagnosis of tuberculosis" 34545/PCT/DK2004/00314
- "Chlamydia trachomatis antigens and their use" PA 2004 01633
- "Malaria Vaccine" WO2004043488
- "Compositions and methods for stabilizing lipid based adjuvant formulations using glycolipids" PA 2004 01070
- "Improved Tuberculosis Vaccines" 36109DK1
- "Freeze-dried Vaccine Adjuvant" 15012/PA 2003 01920
- "Adjuvant combinations of liposomes and mycobacterial lipids for immunization compositions and vaccines" 15010/PA 2003 01046
- "ESAT-6-Ag85B hybrid" (Continuation in part, Plougmann, Vingtoft & Partners ref. No. 20486 US 03)
- "Tuberculosis vaccine and diagnostic based on the *Mycobacterium tuberculosis* ESAT-6 gene family" (PCT/DK00/000039, US application 60/144,011, WO0104151)
- "TB vaccine and diagnostic based on antigens from the *Mycobacterium tuberculosis* cell" (PCT/DK99/00538, US application 09/415,884, WO021983)
- "Nucleic acid fragments and polypeptide fragments derived from *Mycobacterium tuberculosis* II" (PCT/DK98/00438, WO99/24577, US patent application 09/246,191)
- "Nucleic acid fragments and polypeptide fragments derived from *Mycobacterium tuberculosis* I" (PCT/DK98/00132, WO98/44119, US patent application 09/050,739)
- "New Diagnosis skin test for Tuberculosis" (PCT/DK94/00270, WO95/01440, US patent application 08/569,221)
- "A polynucleotide functionally coding for the lhp protein from *Mycobacterium tuberculosis*, its biologically active derivative fragments, as well as methods using the same" (PCT/IB98/01091)
- "Adjuvant combinations for immunization composition and vaccines" (US patent application 09/310,551)

### **International grants:**

- Gates Foundation; Grand Challenge in Global Health (GCGH). "Biomarkers of protective immunity and surrogate markers of TB disease in Africa" (2005-2009)
- Gates Foundation; Grand Challenge in Global Health (GCGH). "Preclinical Evaluation of Post-Exposure TB Vaccine" (2005-2009) (8 partner program coordinated by P. Andersen)
- AERAS Global TB Vaccine Foundation, Research Collaboration Agreement (2005-2007)
- EDCTP "Studies of surrogate markers of drug efficacy, disease activity and relapse in tuberculosis." EDCTP Code 2004.01.T.d1 (2005-2007)
- EU project, Contract LSHP-CT-2003-503367, TBVAC "An integrated project for the design and testing of vaccine candidates against tuberculosis: identification, development and clinical studies". (2004-2008)
- EU project, Contract LSHP-CT-2003-503240, MUVAPRED "Mucosal Vaccines for Poverty Related Diseases" (2004-2008)
- WHO, "Vaccination against Latent Tuberculosis" (2003-2004)
- EU project, Contract ICA4-CT-2002-10052, VACSIS "Host-parasite relationship in susceptibility to tuberculosis" (2002-2005)
- EU project, Contract ICA4-CT-1999-10005; INCO-DEV funding for VACSEL project "Longitudinal human study on development of tuberculosis" (1999-2003)
- NIH project, Contract N01-AI-95383, TBRU consortium application. (1999-2002)
- EU project, Contract QLG2- CT- 1999- 00660: "A functional genomics study of lysyl-tRNA synthesis as a target for the diagnosis and treatment of microbial infections and mitochondrial myopathies" (1999- 2003)
- EU project, Contract ICA4-CT-2000-30023: "Identification of relevant diagnostic antigens for bovine tuberculosis: influences of animal and regional disease patterns" (2000-2003)
- EU project, Contract QLRT-2001-02018: "Structural and functional genomics of *Mycobacterium tuberculosis*" (2002-2004)
- EU project, Contract QLRT-2001-01702: "Novel approaches to induce mucosal immunity against TB using the combined adjuvant strategy of CTA1-DD and ISCOMS" (2001-2004)
- EU project, Contract QLK2-CT-1999-01093 TB Vaccine Cluster (2000-2003)
- EU project (INCO-DEV): Identification of relevant diagnostic antigens for bovine tuberculosis: Influences of animal and regional disease patterns (2000-)
- Partner in the EU programmes "New *Mycobacterium tuberculosis* antigens for diagnosis and vaccines" and "Development of novel vaccines by attenuation of *M. tuberculosis*", co-ordinated by Institut Pasteur (1997-2000)
- EU project, Contract IC18-CT97-0254: "Development of tuberculosis vaccine with consistent efficacy in different regions of the world" (1997-2000)
- EEC STD-3 project, Contract TS3\*CT94-0313: "Development of an improved vaccine against *Mycobacterium tuberculosis*" (1994 - 97)
- WHO, Global Vaccine Programme, "The search for antigens of immunological relevance from *M. tuberculosis*" (1992-97)

**Doctor of Science opponent**

Antigens of *Mycobacterium avium* subspecies *paratuberculosis*, **I. Olsen**, Oslo, Norway 2001

**PhD. opponent**

Augmentation of adenovirus induced immune responses Evaluation of administration and antigen presentation with respect to the DC8+ T cell mediated immune response induced by replication defective adenovirus, **P. J. Holst**, Copenhagen, Denmark, 2008

Cellular Immune Responses during Latent Tuberculosis, **E. M. S. Leyten**, The Hague, The Netherlands, 2008

Antiviral Protection by Monospecific CD8 T Cells Primed through DNA Immunization, **C. Bartholdy**, Copenhagen, Denmark, 2003

Cytokines as potential co-adjuvants in a subunit vaccine against tuberculosis, **I. S. Leal**, Porto, Portugal, 2001

The interplay of cytokines and chemokines in virus-induced T-cell mediated inflammation, **A. Nansen**, Copenhagen, Denmark, 2000

Identification of novel *Leishmania* antigens and development of a DNA vaccine against leishmaniasis, **A.T.R. Jensen**, Copenhagen, Denmark 2000

**MSc assessments**

The pathogenesis of experimental malaria (thesis in Danish), **N.S. Sørensen**, Copenhagen Denmark, 1996

Investigation of the human immune response to antigens isolated from actively-growing *Mycobacterium tuberculosis* (thesis in Danish), **H. T. Boesen**, Copenhagen, Denmark 1994

**PhD. supervision**

On the mechanisms of selected adjuvants, **K.K. Smith**, Copenhagen, Denmark, 2007

Identification of Markers of Apoptosis as Correlates of Protection or Susceptibility in Tuberculosis, **M. A. Alemayehu**, Copenhagen, Denmark 2007

Antigenic Profiling of *Chlamydia trachomatis*, **F. Föllmann**, Copenhagen, Denmark, 2007

Pre-clinical evaluation and characterisation of adjuvant formulation in novel subunit vaccines against *Mycobacterium tuberculosis*, **E.A. Agger**, Copenhagen Denmark, 2006

Immune recognition of novel antigens from *M. tuberculosis* with potential vaccine and diagnostic utility, **A. Demissie Areg**, Copenhagen, Denmark, 2004

Vaccination against tuberculosis with the mycobacterial antigen, ESAT-6 in naïve and sensitised mice, **L. Brandt**, Copenhagen, Denmark, 2000

Identification, purification and characterization of *Mycobacterium tuberculosis* culture filtrate proteins, **K. Weldingh**, Copenhagen Denmark, 1999

Immunity against *Mycobacterium Tuberculosis* in Humans, **P. Ravn**, Copenhagen, Denmark 1996

**MSc supervision**

An immunological Investigation of the DDA/TDB-Adjuvant, **K.V. Knudsen**, Copenhagen, Denmark 2002

Immunological characterisation of subcellular fractions from *Mycobacterium tuberculosis*, **E.A. Agger**, Copenhagen, 1998

## Publications

1. Lillebaek T, Bergstedt W, Tingskov PN, Thierry-Carstensen B, Aggerbeck H, Hoff ST, Weldingh K, **Andersen P**, Soeborg B, Thomsen VO, Andersen AB. Risk of sensitization in healthy adults following repeated administration of rdESAT-6 skin test reagent by the Mantoux injection technique. *Tuberculosis (In Press)*
2. Werninghaus K, Babiak A, Gro O, Hlscher C, Dietrich H, Agger EM, Mages J, Mocsai A, Schoenen H, Finger K, Nimmerjahn F, Brown GD, Kirschning C, Heit A, **Andersen P**, Wagner H, Ruland J, Lang R. Adjuvanticity of a synthetic cord factor analogue for subunit *Mycobacterium tuberculosis* vaccination requires FcR $\gamma$ -Syk-Card9-dependent innate immune activation. *J Exp Med.* 2009 Jan 16;206(1):89-97
3. Morera Y, Bequet-Romero M, Ayala M, Lamdán H, Agger EM, **Andersen P**, Gavilondo JV. Anti-tumoral effect of active immunotherapy in C57BL/6 mice using a recombinant human VEGF protein as antigen and three chemically unrelated adjuvants. *Angiogenesis.* 2008;11(4):381-93
4. Andersen CS, Agger EM, Rosenkrands I, Gomes JM, Bhowruth V, Gibson KJC, Petersen RV, Minnikin DE, Besra GS, **Andersen P**. A simple mycobacterial monomycoated glycerol lipid has potent immunostimulatory activity. *J Immunol.* 2009 Jan 1;182(1):424-432
5. Kamath AT, Rochat AF, Valenti MP, Agger EM, Lingnau K, **Andersen P**, Lambert PH, Siegrist CA. Adult-like Anti-Mycobacterial T Cell and in vivo Dendritic Cell Responses following Neonatal Immunization with Ag85B-ESAT-6 in the IC31® Adjuvant. *PLoS ONE.* 2008;3(11):e3683
6. Ciabattini A, Pettini E, **Andersen P**, Pozzi G, Medaglini D. Primary activation of antigen-specific naïve CD4+ and CD8+ T cells following intranasal vaccination with recombinant bacteria. *Infect Immun.* 2008 Dec;76(12):5817-25
7. Christensen D, Allesø M, Rosenkrands I, Rantanen J, Foged C, Agger EM, **Andersen P**, Nielsen HM. NIR transmission spectroscopy for rapid determination of lipid and lyoprotector content in liposomal vaccine adjuvant system CAF01. *Eur J Pharm Biopharm.* 2008 Nov;70(3):914-20.
8. Wassie L, Demissie A, Aseffa A, Abebe M, Yamuah L, Tilahun H, Petros B, Rook G, Zumla A, **Andersen P**, Doherty TM; for the VACSEL Study Group. Ex Vivo Cytokine mRNA Levels Correlate with Changing Clinical Status of Ethiopian TB Patients and their Contacts Over Time. *PLoS ONE* 3(1): e1522.
9. Rosenkrands I, Aagaard C, Weldingh K, Brock I, Dziegiel MH, Singh M, Hoff S, Ravn P, **Andersen P**. Identification of Rv0222 from RD4 as a novel serodiagnostic target for tuberculosis. *Tuberculosis (Edinb).* 2008 Jul;88(4):335-43
10. Agger EM, Rosenkrands I, Hansen J, Brahimi K, Vandahl BS, Aagaard C, Werninghaus K, Kirschning C, Lang R, Christensen D, Tholstrup T, Færge E, Færge T

for (CAF01): a versatile adjuvant for vaccines with different immunological requirements. *PLoS ONE*. 2008 Sep 8;3(9):e3116

11. Kirby DJ, Rosenkrands I, Agger EM, **Andersen P**, Coombes AG, Perrie Y. Liposomes act as stronger sub-unit vaccine adjuvants when compared to microspheres. *J Drug Target*. 2008 Aug;16(7):543-54.
12. Hansen J, Jensen KT, Follmann F, Agger EM, Theisen M, **Andersen P**. Liposome delivery of *C. muridarum* MOMP primes a Th1 response that protect against genital Chlamydia infection in a mouse model. *J Infect Dis*. 2008 Sep 1;198(5):758-67.
13. Christensen D, Kirby D, Foged C, Agger EM, **Andersen P**, Perrie Y, Nielsen HM.  $\alpha$ , $\alpha'$ -trehalose 6,6'-dibehenate in non-phospholipid-based liposomes enables direct interaction with trehalose, offering stability during freeze-drying. *Biochim Biophys Acta*. 2008 May;1778(5):1365-1373.
14. Arend SM, Franken WP, Aggerbeck H, Prins C, van Dissel JT, Thierry-Carstensen B, Tingskov PN, Weldingh K, **Andersen P**. Double-blind randomized Phase I study comparing rdESAT-6 to tuberculin as skin test reagent in the diagnosis of tuberculosis infection. *Tuberculosis (Edinb)*. 2008 May;88(3):249-61.
15. Agger EM, Cassidy JP, Brady J, Korsholm KS, Vingsbo-Lundberg C, **Andersen P**. Adjuvant modulation of the cytokine balance in *Mycobacterium tuberculosis* subunit vaccines: immunity, pathology and protection. *Immunology*. 2008 Jun;124(2):175-85
16. Weldingh K, **Andersen P**. ESAT-6/CFP10 skin test predicts disease in *M. tuberculosis*-infected guinea pigs. *PLoS ONE*. 2008 Apr 23;3(4):e1978.
17. Kamath AT, Valenti MP, Rochat AF, Agger EM, Lingnau K, von Gabain A, **Andersen P**, Lambert PH, Siegrist CA. Protective anti-mycobacterial T cell responses through exquisite in vivo activation of vaccine-targeted dendritic cells. *Eur J Immunol*. 2008 May;38(5):1247-56
18. Kirby DJ, Rosenkrands I, Agger EM, **Andersen P**, Coombes AG, Perrie Y. PLGA microspheres for the delivery of a novel subunit TB vaccine. *J Drug Target*. 2008 May;16(4):282-93.
19. Follmann F, Olsen AW, Jensen KT, Hansen PR, **Andersen P**, Theisen M. Antigenic profiling of a *Chlamydia trachomatis* gene-expression library. *J Infect Dis*. 2008 Mar 15;197(6):897-905
20. **Andersen P**, Kaufmann SHE. Novel Vaccination Strategies against Tuberculosis, Chapter 7.1 for Volume 2, *Handbook of Tuberculosis, Immunology and Cell Biology*, 1. Edition - January 2008, ISBN-13: 978-3-527-31887-2 - Wiley-VCH, Weinheim
21. Olsen AW, Follmann F, Højrup P, Leah R, Sand C, **Andersen P**, Theisen M. Identification of human T-cell targets recognized during the *Chlamydia trachomatis* genital infection. *J Infect Dis*. 2007 Nov 15;196(10):1546-52

in Denmark detected by *M. tuberculosis* specific IFN-gamma whole-blood test. *Scand J Infect Dis.* 2007;39(6-7):554-9.

23. Christensen D, Korsholm KS, Rosenkrands I, Lindenstrom T, **Andersen P**, Agger EM. Cationic liposomes as vaccine adjuvants. *Expert Rev Vaccines.* 2007 Oct;6(5):785-796.
24. **Andersen P.** Tuberculosis vaccines – an update, *Microbiologist*, 2007 Sep;8(73):36-9
25. Billeskov R, Vingsbo-Lundberg C, **Andersen P**, Dietrich J. Induction of CD8 T Cells against a Novel Epitope in TB10.4: Correlation with Mycobacterial Virulence and the Presence of a Functional Region of Difference-1. *J Immunol.* 2007 Sep 15;179(6):3973-81
26. Lyashchenko KP, Greenwald R, Esfandiari J, Greenwald D, Nacy CA, Gibson S, Didier PJ, Washington M, Szczerba P, Motzel S, Handt L, Pollock JM, McNair J, **Andersen P**, Langemans JA, Verreck F, Ervin S, Ervin F, McCombs C. PrimaTB STAT-PAK(R) Assay, a Novel Rapid Lateral-Flow Test for Tuberculosis in Non-human Primates. *Clin Vaccine Immunol.* 2007 Sep;14(9):1158-64.
27. Hoff ST, Abebe M, Ravn P, Range NS, Malenganisho WL, Rodrigues DS, Kallas EG, Søborg C, Doherty TM, **Andersen P**, Weldingh K. Evaluation of Mycobacterium tuberculosis-specific Antibody responses in populations with different levels of exposure from Tanzania, Ethiopia, Brazil and Denmark, *Clin Infect Dis.* 2007 Sep 1;45(5):575-82
28. **Andersen P.** Tuberculosis vaccines – an update, *Nature Reviews Microbiology* 2007 Jul;5(7):484-7
29. Darrah PA, Patel DT, De Luca PM, Lindsay RW, Davey DF, Flynn BJ, Hoff ST, **Andersen P**, Reed SG, Morris SL, Roederer M, Seder RA. Multifunctional TH1 cells define a correlate of vaccine-mediated protection against *Leishmania major*. *Nat Med.* 2007 Jul;13(7):843-50.
30. Christensen D, Foged C, Rosenkrands I, Nielsen HM, **Andersen P**, Agger EM. Trehalose Preserves DDA/TDB Liposomes and their Adjuvant Effect during Freeze-drying, *Biochim Biophys Acta.* 2007 May 13; 1768:2120-29
31. Soborg B, Andersen AB, Larsen HK, Weldingh K, **Andersen P**, Køristian Kofoed K, Ravn P. Detecting a low prevalence of latent tuberculosis among health care workers in Denmark detected by *M. tuberculosis* specific IFN-γ whole-blood test. *Scand. J. Infect. Dis.*, 2007 Jun;39(6):554-9
32. Hohn H, Kortsik C, Zehbe I, Hitzler WE, Kayser K, Freitag K, Neukirch C, **Andersen P**, Doherty TM, Maeurer M. MHC class II Tetramer Guided Detection of Mycobacterium tuberculosis-specific CD4(+) T Cells in Peripheral Blood from Patients with Pulmonary Tuberculosis. *Scand J Immunol.* 2007 May;65(5):467-78
33. **Andersen P**, Doherty TM, Pai M, Weldingh K. The prognosis of latent tuberculosis: can disease be predicted? *Trends Mol Med.* 2007 May;13(5):175-82
34. Korsholm K, Agger E M, Foged C, Christensen D, Dietrich J, Andersen C, Geisler,

35. Dietrich J, Billeskov R, Doherty TM, **Andersen P**. Synergistic effect of bacillus calmette guerin and a tuberculosis subunit vaccine in cationic liposomes: increased immunogenicity and protection. *J Immunol*. 2007 Mar 15;178(6):3721-30.
36. **Andersen P**. Vaccine strategies against latent tuberculosis infection. *Trends Microbiol*. 2007 Jan;15(1):7-13
37. Aagaard C, Govaerts M, Meikle V, Vallecillo AJ, Gutierrez-Pabello JA, Suarez-Guemes F, McNair J, Cataldi A, Espitia C, **Andersen P**, Pollock JM. Optimizing antigen cocktails for *Mycobacterium bovis* Diagnosis in Herds with Different Disease Prevalence: ESAT6/CFP10 Mixture shows Optimal Sensitivity and Specificity. *J Clin Microbiol*. 2006 Dec;44(12):4326-35.
38. Andersen CS, Dietrich J, Agger EM, Lycke NY, Lovgren K, **Andersen P**. The combined CTA1-DD/ISCOMs vector is an effective intranasal adjuvant for boosting prior BCG immunity to *Mycobacterium tuberculosis*. *Infect Immun*. 2007 Jan;75(1):408-16
39. Bennekov T, Dietrich J, Rosenkrands I, Stryhn A, Doherty TM, **Andersen P**. Alteration of epitope recognition pattern in Ag85B and ESAT-6 has a profound influence on vaccine-induced protection against *Mycobacterium tuberculosis*. *Eur J Immunol*. 2006 Dec;36(12):3346-55
40. Jensen KT, Petersen L, Falk S, Iversen P, **Andersen P**, Theisen M, Krogh A. Novel overlapping coding sequences in *Chlamydia trachomatis*. *FEMS Microbiol Lett*. (265(1):106-117
41. Olsen AW, Follmann F, Jønson KT, Højrup P, Leah R, Sørensen H, **Andersen P**, Theisen M. Identification of CT521 as a frequent target of Th1 cells in patients with *Chlamydia trachomatis* infection. *J Infect Dis*. 2006 Nov 1;194(9):1258-66.
42. Dietrich J, Andersen C, Rappuoli R, Doherty TM, Jensen CG, **Andersen P**. Mucosal Administration of Ag85B-ESAT-6 Protects against Infection with *Mycobacterium tuberculosis* and Boosts Prior Bacillus Calmette-Guerin Immunity. *J Immunol*. 2006 Nov 1;177(9):6353-60.
43. Leyten EM, Lin MY, Franken KL, Friggen AH, Prins C, van Meijgaarden KE, Voskuil MI, Weldingh K, **Andersen P**, Schoolnik GK, Arend SM, Ottenhoff TH, Klein MR. Human T-cell responses to 25 novel antigens encoded by genes of the dormancy regulon of *Mycobacterium tuberculosis*. *Microbes Infect*. 2006 Jul;8(8):2052-60.
44. Al-Attiyah R, Madi N, El-Shamy AS, Wiker H, **Andersen P**, Mustafa A. Cytokine profiles in tuberculosis patients and healthy subjects in response to complex and single antigens of *Mycobacterium tuberculosis*. *FEMS Immunol Med Microbiol*. 2006 Jul;47(2):254-61.
45. Lyashchenko KP, Greenwald R, Esfandiari J, Olsen JH, Ball R, Dumonceaux G, Dunker F, Buckley C, Richard M, Murray S, Payeur JB, **Andersen P**, Pollock JM, Mikota S, Miller M, Sofranko D, Waters WR. Tuberculosis in Elephants: Antibody Responses to Defined Antigens of *Mycobacterium tuberculosis*, Potential for

46. Waters WR, Palmer MV, Thacker TC, Bannantine JP, Vordermeier HM, Hewinson RG, Greenwald R, Esfandiari J, McNair J, Pollock JM, **Andersen P**, Lyashchenko KP. Early Antibody Responses to Experimental *Mycobacterium bovis* Infection of Cattle. *Clin Vaccine Immunol*. 2006 Jun;13(6):648-54.

47. Waters WR, Palmer MV, Thacker TC, Payeur JB, Harris NB, Minion FC, Greenwald R, Esfandiari J, **Andersen P**, McNair J, Pollock JM, Lyashchenko KP. Immune Responses to Defined Antigens of *Mycobacterium bovis* in Cattle Experimentally Infected with *Mycobacterium kansasii*. *Clin Vaccine Immunol*. 2006 Jun;13(6):611-9.

48. Vangala A, Kirby D, Rosenkrands I, Agger EM, **Andersen P**, Perrie Y. A comparative study of cationic liposome and niosome-based adjuvant systems for protein subunit vaccines: characterisation, environmental scanning electron microscopy and immunisation studies in mice. *J Pharm Pharmacol*. 2006 Jun;58(6):787-99.

49. Demissie A, Wassie L, Abebe M, Aseffa A, Rook G, Zumla A, **Andersen P**, Doherty TM; VACSEL Study Group. The 6-kilodalton early secreted antigenic target-responsive, asymptomatic contacts of tuberculosis patients express elevated levels of interleukin-4 and reduced levels of gamma interferon. *Infect Immun*. 2006 May;74(5):2817-22.

50. Dietrich J, Vingsbo-Lundberg C, **Andersen P**. TB vaccine strategies – what is needed to solve a complex problem? *Tuberculosis (Edinb)*. 2006 May 3;86(3-4):163-168

51. Agger EM, Rosenkrands I, Olsen AW, Hatch G, Williams A, Kritsch C, Lingnau K, von Gabain A, Andersen CS, Korsholm KS, **Andersen P**. Protective immunity to tuberculosis with Ag85B-ESAT-6 in a synthetic cationic adjuvant system IC31. *Vaccine*. 2006 Jun 29;24(26):5452-60.

52. Leyten EM, Mulder B, Prins C, Weldingh K, **Andersen P**, Ottenhoff TH, van Dissel JT, Arend SM. Use of enzyme-linked immunospot assay with *Mycobacterium* tuberculosis-specific peptides for diagnosis of recent infection with *M. tuberculosis* after accidental laboratory exposure. *J Clin Microbiol*. 2006 Mar;44(3):1197-201.

53. Demissie A, Leyten EM, Abebe M, Wassie L, Aseffa A, Abate G, Fletcher H, Owiafe P, Hill PC, Brookes R, Rook G, Zumla A, Arend SM, Klein M, Ottenhoff TH, **Andersen P**, Doherty TM; the VACSEL Study Group. Recognition of stage-specific mycobacterial antigens differentiates between acute and latent infections with *Mycobacterium tuberculosis*. *Clin Vaccine Immunol*. 2006 Feb;13(2):179-86.

54. Dietrich J, Weldingh K, and **Andersen P**. Prospects for a novel vaccine against TB. *Microbes and Infection*  
*Vet Microbiol*. 2006 Feb 25;112(2-4):163-9

55. Davidsen J, Rosenkrands I, Christensen D, Vangala A, Kirby D, Perrie Y, Agger EM, **Andersen P**. Characterization of cationic liposomes based on dimethyldioctadecylammonium and synthetic cord factor from *M. tuberculosis*

antibody responses.  
Biochim Biophys Acta. 2005 Dec 10;1718(1-2):22-31.

56. Rothel JS and **Andersen P**. Diagnosis of latent *Mycobacterium tuberculosis* infection: is the demise of the Mantoux test imminent? Expert Rev Anti Infect Ther. 2005 Dec;3(6):981-93.

57. Doherty TM, **Andersen P**. Vaccines for tuberculosis: novel concepts and recent progress. Clin Microbiol Rev. 2005 Oct;18(4):687-702.

58. Rosenkrands I, Agger EM, Olsen AW, Korsholm KS, Andersen CS, Jensen KT, **Andersen P**. Cationic liposomes containing mycobacterial lipids: a new powerful Th1 adjuvant system. Infect Immun. 2005 Sep;73(9):5817-26.

59. **Andersen P** and Doherty TM. Learning from BCG - Designing a better tuberculosis vaccine. Discovery Medicine 2005. Aug;5(28):383-387

60. Weldingh K, **Andersen P**. Replacing the tuberculin skin test with a specific blood test. Kekkaku. 2005 Aug;80(8):581-5. Japanese.

61. Ravn P, Brock I, **Andersen P**, Weldingh K. A possible successor of the Mantoux test after 97 years. Ugeskr Laeger. 2005 Aug 8;167(32):2905-6.

62. **Andersen, P.** and Doherty, T. M. The success and failure of BCG - implications for a novel tuberculosis vaccine. Nat Rev Microbiol. 2005 Aug;3(8):656-62. Review.

63. Waters, W.R., Palmer, M.V., Bannantine, J.P., Greenwald, R., Esfandiari, J., **Andersen, P**, McNair, J., Pollock, J.M., Lyashchenko, K.P. Antibody Responses in Reindeer (*Rangifer tarandus*) Infected with *Mycobacterium bovis*. Clin Diagn Lab Immunol. 2005 Jun;12(6):727-35.

64. Weldingh, K., Rosenkrands, I., Okkels, L.M., Doherty, T.M., **Andersen, P.** (2005). Assessing the serodiagnostic potential of 35 *Mycobacterium tuberculosis* proteins and identification of four novel serological antigens. J Clin Microbiol. 43:57-65.

65. Dietrich, J., Aagaard, C., Leah, R., Doherty, T. M. and **Andersen, P.** Exchanging ESAT6 with TB10.4 in an Ag85B fusion molecule-based tuberculosis subunit vaccine: efficient protection and ESAT6-based sensitive monitoring of vaccine efficacy. J Immunol. 2005 May 15;174(10):6332-9.

66. **Andersen P**, Doherty TM. TB subunit vaccines - putting the pieces together. Microbes Infect. 2005 May;7(5-6):911-21. Epub 2005 Apr 14. Review.

67. Langermans, J. A. M., Doherty, T. M., Vervenne, R. A. W., van der Laan, T., Lyashchenko, K., Greenwald, R., Agger, E. M., Aagaard, C., Weiler, H., van Soolingen, D., Thomas, A. W., **Andersen, P.** Protection of macaques against *Mycobacterium tuberculosis* infection by a subunit vaccine based on a fusion protein of antigen 85B and ESAT-6. Vaccine. 2005 Apr 15;23(21):2740-50.

68. Ravn P, Munk ME, Andersen AB, Lundgren B, Lundgren JD, Nielsen LN, Kok-Jensen A, **Andersen P**, Weldingh K. Prospective evaluation of a whole-blood test using *Mycobacterium tuberculosis*-specific antigens ESAT-6 and CFP-10 for diagnosis of active tuberculosis. Clin Diagn Lab Immunol. 2005 Apr;12(4):491-6

69. T. M. Doherty, A. Demissie, R. Menzies, **P. Andersen**, G. Rook, A. Zumla, and the MACSEL study group. *Antibodies to ESAT-6 and CFP-10 in the diagnosis of active tuberculosis*. *Am J Respir Crit Care Med*. 2005;172(12):1421-1427.

quantitative PCR.  
J Immunol Methods. 2005 Mar;298(1-2):129-41

70. Arend, S. M., de Haas, P., Leyten, E., Rosenkrands, I., Rigouts, L., **Andersen, P.**, Mijs, W., van Dissel, J. T., van Soolingen, D.: ESAT-6 and CFP-10 in clinical versus environmental isolates of *Mycobacterium kansasii*. J Infect Dis. 2005 Apr 15;191(8):1301-10. Epub 2005 Mar 15.

71. Williams, A., Hatch, G. J., Clark, S. O., Gooch, K. E., Hatch, K. A., Hall, G. A., Huygen, K., Ottenhoff, T. H. M., Franken, K. L. M. C., **Andersen, P.**, Doherty, T. M., Kaufmann, S. H. E., Grode, L., Seiler, P., Martin, C., Gicquel, B., Cole, S. T., Brodin, P., Pym, A. S., Dalemans, W., Cohen, J., Lobet, Y., Goonetilleke, N., McShane, H., Hill, A., Parish, T., Smith, D., Stoker, N., Lowrie, D.B., Källenius, G., Svenson, S., Pawlowski1, A., Marsh, P. D. Evaluation of vaccines in the EU TB Vaccine Cluster using a guinea pig aerosol infection model of tuberculosis. *Tuberculosis (Edinb)*. 2005 Jan-Mar;85(1-2):29-38. Epub 2005 Jan 20.

72. Doherty, T. M., Olsen, A.W. Weischenfeldt, J., Huygen, K., D'Souza, S., Kondratieva, T. K., Yeremeev, V. V., Apt, A. S., Raupach, B., Grode, L., Kaufmann, S. and **Andersen, P.** Comparative analysis of different vaccine constructs bearing antigens from *M. tuberculosis*. J Infect Dis. 2004 Dec 15;190(12):2146-2153.

73. Kanaujia, G.V., Motzel, S., Garcia, M.A., **Andersen, P.**, Gennaro M.L. Recognition of ESAT-6 sequences by antibodies in sera of tuberculous nonhuman primates. Clin Diagn Lab Immunol. 11: 222-6, 2004.

74. Agaard, C., Brock, I., Olsen, A., Ottenhoff, T.H.M., Weldingh, K., **Andersen, P.** Mapping immune reactivity toward Rv2653 and Rv2654: two novel low-molecular-mass antigens found specifically in the *Mycobacterium tuberculosis* complex. J. Infect. Dis., 189: 812-9, 2004.

75. Brock, I., Weldingh, K., Leyten, E.M.S., Arend, S.M., Ravn, P., **Andersen, P.** Specific T-cell epitopes for immunoassay-based diagnosis of *Mycobacterium tuberculosis* infection. J. Clin. Microbiol. 42: 2379-87, 2004.

76. Brock, I., Weldingh, K., Lillebaek, T., Follmann, F., **Andersen, P.** Comparison of tuberculin skin test and new specific blood test in tuberculosis contacts. Am. J. Respir. Crit. Care Med., 170: 65-9, 2004.

77. Vervenne, R.A., Jones, S.L., Soolingen, D.v.D., van der Laan, T. **Andersen, P.**, Heidt, P.J. Thomas, A.W., Langermans, J.A. TB diagnosis in non-human primates: comparison of two interferon-gamma assays and the skin test for identification of *Mycobacterium tuberculosis* infection. Vet. Immunol. Immunopathol., 100: 61-71, 2004.

78. Demissie, A., Abebe, M., Aseffa, A., Rook, G., Fletcher, H., Zumla A., Weldingh, K., Brock, I., **Andersen, P.**, Doherty, T.M., VACSEL Study Group. Healthy individuals that control a latent infection with *Mycobacterium tuberculosis* express high levels of Th1 cytokines and the IL-4 antagonist IL-4delta2. J. Immunol., 172: 6938-43, 2004.

79. Lyashchenko, K., Whelan, A.O., Greenwald, R., Pollock, J.M., **Andersen, P.**, Hewinson, R.G., Vordermeier, H.M. Association of tuberculin-boosted antibody responses with pathology and cell-mediated immunity in cattle vaccinated with *Mycobacterium bovis* BCG and infected with *M. bovis*. Infect. Immun., 72: 2462-7, 2004.

80. Okkels, L.M., **Andersen, P.** Protein-protein interactions of proteins from the ESAT-6 family of *Mycobacterium tuberculosis*. J. Bacteriol., 186: 2487-91, 2004.

81. Holten-Andersen, L., Doherty, T.M., Korsholm, K.S., **Andersen, P.** Combination of the cationic surfactant dimethyl dioctadecyl ammonium bromide and synthetic mycobacterial cord factor as an efficient adjuvant for tuberculosis subunit vaccines. *Infect. Immun.*, 72: 1608-17, 2004.

82. Olsen, A.W., Brandt, L., Agger, E.M., van Pinxteren, L.A.H., **Andersen, P.** The Influence of Remaining Live BCG Organisms in Vaccinated Mice on the Maintenance of Immunity to Tuberculosis. *Scand. J. Immun.*, 60: 273-7, 2004.

83. Ravn, P., Munk, M.E., Andersen, A.B., Lundgren, B., Nielsen, L.N., Lillebaek, T., Soerensen, I.J., **Andersen, P.**, Weldingh, K. Reactivation of tuberculosis during immunosuppressive treatment in a patient with a positive QuantiFERON-RD1 test. *Scand. J. Infect. Dis.*, 36: 499-501, 2004.

84. Shams, H., Klucar, P., Weis, S.E., Lalvani, A., Moonan, P.K., Safi, H., Wizel, B., Ewer, K., Nepom, G.T., Lewinsohn, D.M., **Andersen, P.**, Barnes, P.F. Characterization of a *Mycobacterium tuberculosis* peptide that is recognized by human CD4+ and CD8+ T cells in the context of multiple HLA alleles. *J. Immunol.*, 173: 1966-77, 2004.

85. Olsen, A.W., Williams, A., Okkels, L.M., Hatch, G., **Andersen, P.** Protective Effect of a Tuberculosis Subunit Vaccine Based on a Fusion of Ag85B and ESAT-6 in the Aerosol Guinea Pig Model. *Infection and Immunity*, 72: 6148-50, 2004.

86. Brodin, P., Rosenkrands, I., **Andersen, P.**, Cole, S.T., Brosch, R. ESAT-6 proteins: protective antigens and virulence factors? *Trends Microbiol.*, 12: 500-8, 2004.

87. Waters, W.R., Palmer, M.V., Bannantine, J.P., Whipple, D.L., Greenwald, R., Esfandiari, J., **Andersen, P.**, McNair, J., Pollick, J.M., Lyashchenko, K.P. Antigen recognition by serum antibodies in white-tailed deer (*Odocoileus virginianus*) experimentally infected with *Mycobacterium bovis*. *Clin. Diagn. Lab. Immunol.*, 11: 849-55, 2004.

88. Okkels, L.M., Müller, E.C., Schmid, M., Rosenkrands, I., Kaufmann, S.H., **Andersen, P.**, Jungblut, P.R. CFP10 discriminates between nonacetylated and acetylated ESAT-6 of *Mycobacterium tuberculosis* by differential interaction. *Proteomics*, 4: 2954-2960, 2004.

89. Okkels, L.M., Doherty, T.M., **Andersen, P.** Selecting the Components for a Safe and Efficient Tuberculosis Subunit Vaccine - Recent Progress and Post-Genomic Insights. *Curr. Pharm. Biotechnol.*, 4: 69-83, 2003.

90. Olsen, A.W., **Andersen, P.** A novel TB vaccine; strategies to combat a complex pathogen. *Immunology Letters* 85: 207-211, 2003.

91. Rolinck-Werninghaus, C., Magdorf, K., Stark, K., Lyashchenko, K., Gennaro, M.L., Colangeli, R., Doherty, T.M., **Andersen, P.**, Plum, G., Herz, U., Renz, U., Wahn, U. The potential of recombinant antigens ESAT-6, MPT63 and *mig* for specific discrimination of *Mycobacterium tuberculosis* and *M. avium* infection. *Eur. J. Pediat.* 162: 534-6, 2003.

92. Mustafa, A.S., Shaban, F.A., Al-Attiyah, R., Abal, A.T., El-Shamy, A.M., **Andersen, P.**, Oftung, F. Human Th1 cell lines recognize the *Mycobacterium tuberculosis* ESAT-6 antigen and its peptides in association with frequently expressed HLA class II molecules. *Second. Immunol.* 67: 125-131, 2003.

93. Ewer, E., Deeks, J., Alvarez, L., Bryant, G., Waller, S., **Andersen, P.**, Monk, P., Lalvani, A. Comparison of T-cell-based assay with tuberculin skin test for diagnosis of *Mycobacterium tuberculosis* infection in a school tuberculosis outbreak. *The Lancet* 361: 1168-1173, 2003.

94. Pollock, J.M., McNair, J., Bassett, H., Cassidy, J.P., Costello, E., Aggerbeck, H., Rosenkrands, I., **Andersen, P.** Specific Delayed-Type Hypersensitivity Responses to ESAT-6 Identify Tuberculosis-Infected Cattle. *Journ. Clin. Microbiol.*, 41: 1856-60, 2003.

95. Black, G.F., Weir, R.E., Chaguluka, S.D., Warndorff, D., Crampin, A.C., Mwaungulu, L., Sichali, L., Floyd, S., Bliss, L., Jarman, E., Donovan, L., **Andersen, P.**, Britton, W., Hewinson, G., Huygen, K., Paulsen, J., Singh, M., Prestidge, R., Fine, P.E., Dockrell, H.M. Gamma interferon responses induced by a panel of recombinant and purified mycobacterial antigens in healthy, non-mycobacterium bovis BCG-vaccinated Malawian young adults. *Clin. Diagn. Lab. Immunol.*, 10: 602-611, 2003.

96. Greenwald, R., Esfandiari, J., Lesellier, S., Houghton, R., Pollock, J.M., Aagaard, C., **Andersen, P.**, Hewinson, R.G., Chambers, M., Lyashchenko, K. Improved serodetection of *Mycobacterium bovis* infection in badgers (*Meles meles*) using multiantigen test formats. *Diagn. Microbiol. Infect. Dis.*, 46: 197-203, 2003.

97. Aagaard, C., Govaerts, M., Meng Okkels, L., **Andersen, P.**, Pollock, J.M. Genomic approach to identification of *Mycobacterium bovis* diagnostic antigens in cattle. *J. Clin. Microbiol.* 41: 3719-28, 2003.

98. Agger, E.M., Brock, I., Meng Okkels, L., Arend, S.M., Aagaard, C., Weldingh, K.N., **Andersen, P.** Human T-cell responses to the RD1-encoded protein TB27.4 (Rv3878) from *Mycobacterium tuberculosis*. *Immunology*, 2003 Dec;110(4):507-12

99. Okkels, L.M., Brock, I., Follmann, F., Agger, E.M., Arend, S.M., Ottenhoff, T.H.M., Oftung, F., Rosenkrands, I., **Andersen, P.** PPE Protein (RV3873) from DNA Segment RD1 of *Mycobacterium tuberculosis*: Strong Recognition of Both Specific T-Cell Epitopes and Epitopes Conserved within the PPE family. *Infect. Immun.*, 71: 6116-6123, 2003.

100. **Andersen, P.**, Gicquel, B., Huygen, K. Tuberculosis Vaccine Science from Tuberculosis by William N. Rom and Stuart M. Garay, Lippincott Williams & Wilkins, Chapter 59, page 885-898, 2003.

101. Al-Attiyah, R., Mustafa, A.S., Abal A.T., Madi, N.M., **Andersen, P.** Restoration of mycobacterial antigen-induced proliferation and interferon-gamma responses in peripheral blood mononuclear cells of tuberculosis patients upon effective chemotherapy. *FEMS Immunol. Med. Microbiol.*, 38: 249-56, 2003.

102. Buddle, B.M., McCarthy, A.R., Ryan, T.J., Pollock, J.M., Vordermeier, H.M., Hewinson, R.G., **Andersen, P.**, de Lisle, G.W. Use of mycobacterial peptides and recombinant proteins for the diagnosis of bovine tuberculosis in skin test-positive cattle. *Vet. Rec.*, 153: 615-20, 2003.

103. Brandt, L., Feino Cunha, J., Weinreich Olsen, A., Chilima, B., Hirsch, P., Appelberg, R., **Andersen, P.** Failure of the *Mycobacterium bovis* BCG Vaccine: Some Species of Environmental Mycobacteria Block Multiplication of BCG and Induction of Protective Immunity to Tuberculosis. *Infect. Immun.*, 70: 672-678, 2002.

104. Doherty, T.M., Demissie, A., Olobo, J., Waldy, D., Britton, S., Eguale, F., Ravn, P., **Andersen, P.**  
Immune responses to the *Mycobacterium tuberculosis*-Specific Antigen ESAT-6 Signal Subclinical Infection among Contacts of Tuberculosis Patients. *Journ. of Clin. Microbiol.*, 40: 704-706, 2002.

105. Doherty, T.M., **Andersen, P.**  
Tuberculosis vaccine development. *Curr. Opin. Pulm. Med.*, 8: 183-7, Review, 2002.

106. Wedlock, D.N., Keen, D.L., McCarthy, A.R., **Andersen, P.**, Buddle, B.M.  
Effect of different adjuvants on the immune responses of cattle Vaccinated with *Mycobacterium tuberculosis* culture filtrate proteins. *Vet. Immunopathol.*, 86: 79-88, 2002.

107. Doherty, T.M., Olsen, A.W., van Pinxteren, L., **Andersen, P.**  
Oral vaccination with subunit vaccines protects animals against aerosol infection with *Mycobacterium tuberculosis*. *Infect. Immun.*, 70: 3111-21, 2002.

108. Rosenkrands, I., Slayden, R.A., Crawford, J., Aagaard, C., Barry, C.E. 3rd, **Andersen, P.**  
Hypoxic response of *Mycobacterium tuberculosis* studied by metabolic labeling and proteome analysis of cellular and extracellular proteins. *J. Bacteriol.*, 184: 3485-91, 2002.

109. Skjøt, R.L.V., Brock, I., Arend, S.M., Munk, M.E., Theisen, M., Ottenhoff, T.H.M., **Andersen, P.**  
Epitope Mapping of the Immunodominant Antigen TB10.4 and the Two Homologous Proteins TB10.3 and TB12.9, Which Constitute a Subfamily of the esat-6 Gene Family. *Infect. Immun.*, 70: 5446-5453 , 2002.

110. Agger, E.M., Weldingh, K., Olsen, A.W., Rosenkrands, I., **Andersen, P.**  
Specific Acquired Resistance in Mice Immunized with Killed Mycobacteria. *Scand. J. Immunol.*, 56: 443-447, 2002.

111. Johansen IS, Thomsen VØ, Johansen A, **Andersen P**, Lundgren B.  
Evaluation of a new commercial assay for diagnosis of pulmonary and nonpulmonary tuberculosis. *Eur J Clin Microbiol Infect Dis.* 2002 Jun;21(6):455-60. Epub 2002 Jun 14.

112. Agger, E.M., **Andersen P.**  
A novel TB vaccine; towards a strategy based on our understanding of BCG failure. *Vaccine* 21: 7-14, 2002.

113. Geluk, A., Ottenhoff, T.H.M., Arend, S.M., **Andersen, P.**, Doherty, T.M.  
Letter to the Editor, ESAT-6 and CFP-10: What Is the Diagnosis? *Infect. Immun.* 6509-6511, Nov. 2002

114. Welsh, M.D., Kennedy, H.E., Smyth, A.J., Girvin, R.M., **Andersen, P.**, Pollock, J.M.  
Responses of bovine WC1(+) gamma delta T cells to protein and nonprotein antigens of *Mycobacterium bovis*. *Infect. Immun.* 70: 6114-6120, 2002.

115. Wedlock, D.N., Keen, D.L., McCarthy A.R., **Andersen, P.**, Buddle, B.M.  
Effect of different adjuvants on the immune responses of cattle vaccinated with *Mycobacterium tuberculosis* culture filtrate proteins. *Vet. Immunopathol.* 86: 79-88, 2002.

116. Buddle, B.M., Ryan, T.J., Pollock, J.M., **Andersen, P.**, de Lisle, G.W.  
Use of ESAT-6 in the interferon- $\gamma$  test for diagnosis of bovine tuberculosis following skin testing. *Vet. Microbiol.* 80: 27-36, 2001

117. Agger, E.M., **Andersen, P.**  
Tuberculosis subunit vaccine development: on the role of interferon- $\gamma$ . *Vaccine* 19: 2298-2302, 2001.

118. Pollock, J.M., Buddle, B.M., **Andersen, P.**  
Towards more accurate diagnosis of bovine tuberculosis using defined antigens. *Tuberculosis* 81: 65-69, 2001.

119. **Andersen, P.**  
TB vaccines: progress and problems. *Trends in Imm.* 22: 160-168, 2001.

120. Munk, M.E., Arend, S.M., Brock, I., Ottenhoff, T.H.M., **Andersen, P.**  
Use of ESAT-6 and CFP-10 Antigens for Diagnosis of Extrapulmonary Tuberculosis. *JID* 183: 175-6, 2001.

121. Arend, S.M., Ottenhoff, T.H.M., **Andersen, P.**, van Dissel, J.T.  
Uncommon presentations of tuberculosis: the potential value of a novel diagnostic assay based on the *Mycobacterium tuberculosis*-specific antigens ESAT-6 and CFP-10. *Int. J. Tuberc. Lung. Dis.* 5(7): 1-7, 2001.

122. Brock, I., Munk, M.E., Kok-Jensen, A., **Andersen, P.**  
Performance of whole blood IFN- $\gamma$  test for tuberculosis diagnosis based on PPD or the specific antigens ESAT-6 and CFP-10. *Int. J. Tuberc. Lung. Dis.* 5: 462-467, 2001.

123. Olsen, A.W., van Pinxteren, L.A.H., Okkels, L.M., Rasmussen, P.B., **Andersen, P.**  
Protection of Mice with a Tuberculosis Subunit Vaccine Based on a Fusion Protein of Antigen 85B and ESAT-6. *Infect. Immun.* 69: 2773-2778, 2001.

124. Rosenkrands, I., **Andersen, P.**  
Preparation of culture filtrate proteins from *Mycobacterium tuberculosis*, in Parish, T. and N.G. Stoker (eds): *Mycobacterium tuberculosis* protocols. *Methods in Molecular Medicine* 54, 205-215, 2001.

125. Leal, I.S., Flórido, M., **Andersen, P.**, Appelberg, R.  
Interleukin-6 regulates the phenotype of the immune response to a tuberculosis subunit vaccine. *Immunology*, 103: 375-381, 2001.

126. Wu-Hsieh, B.A., Chen, C., Lai, S., Chang, J., Wu, C. H., Cheng, W., **Andersen, P.**, Doherty T. M.  
Long-Lived Immune Response to Early Secretory Antigenic Target 6 in Individuals Who Had Recovered from Tuberculosis. *Clin. Infect. Dis.*, 33: 1336-40, 2001.

127. Doherty, T.M., Munk, M.E., **Andersen, P.**  
Control of Tuberculosis: A Historical Perspective on the Role of Science. In: *Return of the White Plague: Global Poverty and the New Tuberculosis*. Ed.s. M. Gandy, A. Zumla : Publisher: Verso In press, 2001.

128. Skjøt, R., Agger, E.M., **Andersen, P.**  
Antigen Discovery and Tuberculosis Vaccine Development in the Post-genomic Era. *Scand. J. Infect. Dis.* 33: 643-647, 2001.

129. Leal, I.S., Smedegaard, B., **Andersen, P.**, Appelberg, R.  
Failure to induce enhanced protection against tuberculosis by increasing T-cell-dependent interferon- $\gamma$  generation. *Immunology*, 104: 157-161, 2001.

130. Arend, S.M., Engelhard, A.C., Groot, G., de Boer, K., **Andersen, P.**, Ottenhoff, T.H., van Dissel, J.T.  
Tuberculin Skin Testing Compared with T-Cell Responses to *Mycobacterium tuberculosis*-Specific and Nonspecific Antigens for Detection of Latent Infection in Persons with Recent Tuberculosis Contact. *Clin. Diaan. Lab. Immunol.* 8: 1089-

131. Langermans, A.M., **Andersen, P.**, van Soolingen, D., Vervenne, R.A.W., Frost, P.A., van der Laan, T., van Pinxteren, L.A.H., van den Hombergh, J., Kroon, S., Peekel, I., Florquin, S., Thomas, A.W. Divergent effect of bacillus Calmette-Guérin (BCG) vaccination on *Mycobacterium tuberculosis* infection in highly related macaque species: Implications for primate models in tuberculosis vaccine research. *PNAS*, 98: 11497-11502, 2001.

132. Mollenkopf H.J., Groine-Triebkorn, D., **Andersen, P.**, Hess, J., Kaufmann, S.H. Protective efficacy against tuberculosis of ESAT-6 secreted by a live *Salmonella typhimurium* vaccine carrier strain and expressed by naked DNA. *Vaccine*, 19: 4028-35, 2001.

133. Vekemans, J., Lienhardt, C., Sillah, J.S., Wheeler, J.G., Lahai, G.P., Doherty, M.T., Corrah, T., **Andersen, P.**, McAdam, K.P., Marchant, A. Tuberculosis contacts but not patients have higher gamma interferon responses to ESAT-6 than do community controls in The Gambia. *Infect. Immun.*, 69: 6554-7, 2001.

134. Mustafa, A.S., Oftung, F., Amoudy, H.A., Madi, N.M., Abal, A.T., Shaban, F., Rosenkrands, I., **Andersen, P.** Multiple epitopes from the *Mycobacterium tuberculosis* ESAT-6 antigen are recognized by antigen-specific human T cell lines. *Clin. Infect. Dis.*, 30: 201-5, 2000.

135. Brandt, L., Elhay, M.J., Rosenkrands, I., Lindblad, E.B., **Andersen, P.** ESAT-6 subunit vaccination against *Mycobacterium tuberculosis*. *Infect. Immun.*, 68: 791-795, 2000.

136. Rosenkrands, I., Weldingh, K., Jacobsen, S., Hansen, C.V., Florio, W., Gianetra, I., **Andersen, P.** Mapping and identification of *Mycobacterium tuberculosis* proteins by two-dimensional gel electrophoresis, microsequencing and immunodetection. *Electrophoresis* 21: 935-948, 2000.

137. Skjøt, R.L.V., Oettinger, T., Rosenkrands, I., Ravn, P., Brock, I., Jacobsen, S., **Andersen, P.** Comparative evaluation of low-molecular-mass proteins from *Mycobacterium tuberculosis* identifies members of the ESAT-6 family as immunodominant T-cell antigens. *Infect. Immun.*, 68: 214-220, 2000.

138. van Pinxteren, L.A.H., Ravn, P., Agger, E.M., Pollock, J., **Andersen, P.** Diagnosis of Tuberculosis based on the two specific antigens ESAT-6 and CFP10. *Clin. Diagn. Lab. Immunol.*, 7: 155-160, 2000.

139. Weldingh, K., Hansen, A., Jacobsen, S., **Andersen, P.** High resolution electroelution of polyacrylamide gels for the purification of single proteins from *Mycobacterium tuberculosis* culture filtrate. *Scand. J. Immunol.*, 51: 79-86, 2000.

140. **Andersen, P.**, Munk, M.E., Pollock, J.M., Doherty, T.M. Specific immune-based diagnosis of tuberculosis. *Lancet*, 356: 1099-104, 2000. Review

141. Arend, S.M., **Andersen, P.**, van Meijgaarden, K.E., Skjøt R.L., Subronto YW, van Dissel, J.T., Ottenhoff, T.H.M. Detection of active tuberculosis infection by T-cell responses to early-secreted

142. Pollock, J.M., Girvin, R.M., Lightbody, K.A., Clements, R.A., Neill, S.D., Buddle, B.M., **Andersen, P.**  
Assessment of defined antigens for the diagnosis of bovine tuberculosis in skin test-reactor cattle. *Veterinary Record*, 146: 659-65, 2000.

143. Olsen, A.W., Hansen, P.R., Holm, A., **Andersen, P.**  
Efficient protection against *M. tuberculosis* by vaccination with a single subdominant epitope from the ESAT-6 antigen. *Eur. J. Immunol.* 30: 1724-32, 2000.

144. **Andersen, P.**, Smedegaard, B.  
CD4+ T-cell subsets that mediate immunological memory to *Mycobacterium tuberculosis* infection in mice. *Infect. Immun.* 68: 621-629, 2000.

145. Arend, S.M., Geluk, A., Meijgaarden, K.E., Dissel, J.T., Theisen, M., **Andersen, P.**, Ottenhoff, T.  
Antigenic equivalence of human T-cell responses to *M. tuberculosis*-specific RD1-encoded protein antigens ESAT-6 and CFP-10 and culture filtrate protein 10 and to mixtures of synthetic peptides. *Infect. Immun.* 68: 3314-21, 2000.

146. Schwander, S.K., Torres, M., Carranza, C., Escobedo, D., Tary-Lehmann, M., **Andersen, P.**, Toossi, Z., Ellner, J.J., Rich, E.A., Sada, E.  
Pulmonary mononuclear cell responses to antigens of *Mycobacterium tuberculosis* in healthy household contacts of patients with active tuberculosis and healthy controls from the community. *J. Immunol.* 165: 1479-85, 2000.

147. Rosenkrands, I., King, A., Weldingh, K., Moniatte, M., Moertz, E., **Andersen, P.**  
Towards the proteome of *Mycobacterium tuberculosis*. *Electrophoresis* 21: 3740-3756, 2000.

148. van Pinxteren, L.A.H., Cassidy, J.P., Smedegaard, B.H.C., Agger, E.M., **Andersen, P.**  
Control of latent *Mycobacterium tuberculosis* infection is dependent on CD8 T cells. *Eur. J. Immunol.* 30: 3689-3698, 2000.

149. Doherty, T.M., **Andersen, P.**  
Tuberculosis vaccines: developmental work and the future. *Curr. Opin. Pulm. Med.* 6: 203-208, 2000.

150. Mustafa, A.S., Oftung, F., Amoudy, H.A., Madi, N.M., Abal, A.T., Shaban, F., Rosenkrands, I., **Andersen, P.**  
Multiple epitopes from the *Mycobacterium tuberculosis* ESAT-6 antigen are recognized by antigen-specific human T cell lines. *Clin. Infect. Dis.* 30: 201-205, 2000.

151. Smith, S.M., Klein, M.R., Malin, A.S., Sillah, J., Huygen, K., **Andersen, P.**, McAdam, K.P., Dockrell, H.M.  
Human CD8+ T cells specific for *Mycobacterium tuberculosis* secreted antigens in tuberculosis patients and healthy BCG-vaccinated controls in the Gambia. *Infect. Immun.* 68: 7144-8, 2000.

152. Malin, A.S., Huygen, K., Content, J., Mackett, M., Brandt, L., **Andersen, P.**, Smith, S.M., Dockrell, H.M.  
Vaccinia expression of *Mycobacterium tuberculosis*-secreted proteins: tissue plasminogen activator signal sequence enhances expression and immunogenicity of *M. tuberculosis* Ag85. *Microbes Infect.* 2: 1677-85, 2000.

153. Andersen, Å.B., Bauer, J.Ø., **Andersen, P.**  
Tuberkuloseforskning. Ugeskr. Læger 161: 3435-3439, 1999.

T-cell recognition of *Mycobacterium tuberculosis* culture filtrate fractions in tuberculosis patients and their household contacts. *Infect. Immun.* 67: 5967-5971, 1999.

155. Doherty, T.M., **Andersen, P.**  
Tuberculosis vaccines - developmental work and the future. *Curr. Opin. Pulm. Med.* 6: 203-8, 1999.

156. Johnson, P.D.R., Stuart, R.L., Grayson, M.L., Olden, D., Clancy, A., Ravn, P., **Andersen, P.**, Britton, W.J., Rothel, J.S.  
Tuberculin-purified protein derivative-, MTP-64- and ESAT-6- stimulated gamma interferon responses in medical students before and after *Mycobacterium bovis* BCG vaccination and in patients with tuberculosis. *Clin. Diagn. Lab. Immunol.* 6: 934-937, 1999.

157. Leal, I.S., Smedegaard, B., **Andersen, P.**, Appelberg, R.  
Interleukins 6 and 12 participate in the induction of a type 1 protective T cell response during vaccination with a tuberculosis subunit vaccine. *Infect. Immun.* 67: 5747-5754, 1999.

158. Lein, A.D., von Reyn, C.F., Ravn, P., Horsburgh, C.R.Jr., Alexander, L.N., **Andersen, P.**  
Cellular immune responses to ESAT-6 discriminate between patients with pulmonary disease due to *Mycobacterium avium* complex and those with pulmonary disease due to *Mycobacterium tuberculosis*. *Clin. Diagn. Lab. Immunol.* 6: 606-609, 1999.

159. Oettinger, T., Jørgensen, M., Ladefoged, A., Hasløv, K., **Andersen, P.**  
Development of the *Mycobacterium bovis* BCG vaccine: review of the historical and biochemical evidence for a genealogical tree. *Tubercle and Lung Dis.* 79: 243-250, 1999.

160. Ravn, P., Demissie, A., Eguale, T., Wondwossen, H., Lein, D., Arnoudy, H.A., Mustafa, A.S., Jensen, A.K., Holm, A., Rosenkrands, I., Oftung, F., Olobo, J., von Reyn, F., **Andersen, P.**  
Human T cell responses to the ESAT-6 antigen from *Mycobacterium tuberculosis*. *J. Infect. Dis.* 179: 637-645, 1999.

161. Rosenkrands, I., Weldingh, K., Ravn, P., Brandt, L., Højrup, P., Rasmussen, P.B., Coates, A.R., Singh, M., Mascagni, P., **Andersen, P.**  
Differential T-cell recognition of naïve and recombinant *Mycobacterium tuberculosis* GroES. *Infect. Immun.* 67: 5552-5558, 1999.

162. Weldingh, K., **Andersen, P.**  
Immunological evaluation of novel *Mycobacterium tuberculosis* culture filtrate proteins. *FEMS Immunol. Med. Microbiol.* 23: 159-164, 1999.

163. Buddle, B.M., Parlane, N.A., Keen, D.L., Aldwell, F.E., Pollock, J.M., Lightbody, K., **Andersen, P.**  
Differentiation between *Mycobacterium bovis* BCG-vaccinated and *M. bovis*-infected cattle by using recombinant mycobacterial antigens. *Clin. Diag. Lab. Immunol.* 6: 1-5, 1999.

164. Berthet, F.-X., Rasmussen, P.B., Rosenkrands, I., **Andersen, P.**, Gicquel, B.

165. Elhay, M.J., Oettinger, T., **Andersen, P.**  
Delayed-type hypersensitivity responses to ESAT-6 and MPT64 from *Mycobacterium tuberculosis* in the guinea pig. *Infect. Immun.* 66: 3454-3456, 1998.

166. Harboe, M., Wiker, H.G., Ulvund, G., Malin, A.S., Dockrell, H., Holm, A., Jørgensen, M.C., **Andersen, P.**  
B cell epitopes and quantification of the ESAT-6 protein of *Mycobacterium tuberculosis*. *Infect. Immun.* 66: 717-723, 1998.

167. Kaufmann, S.H.E., **Andersen, P.**  
Immunity to mycobacteria with emphasis on tuberculosis: implications for rational design of an effective tuberculosis vaccine. *Immunology of Intracellular Parasitism* (series: *Chem. Immunol.*) 70: 21-59, 1998.

168. Lalvani, A., Brookes, R., Wilkinson, R.J., Malin, A.S., Pathan, A.A., **Andersen, P.**, Dockrell, H., Paisvol, G. & Hill, A.  
Human cytolytic and interferon- $\gamma$ -secreting CD8 $+$  T lymphocytes specific for *Mycobacterium tuberculosis*. *Proc. Natl. Acad. Sci.* 95: 270-275, 1998.

169. Mustafa, A.S., Amoudy, H.A., Wiker, H.G., Abal, A.T., Ravn, P., Oftung, F., **Andersen, P.**  
Comparison of antigen specific T-cell responses of tuberculosis patients using complex or single antigens of *Mycobacterium tuberculosis*. *Scand. J. Immunol.* 48: 535-543, 1998.

170. Pais, T.F., Silva, R., Smedegaard, B., Appelberg, R., **Andersen, P.**  
Analysis of T cells recruited during delayed-type hypersensitivity to purified protein derivative (PPD) versus challenge with tuberculosis infection. *Immunology* 95: 69-75, 1998.

171. Rosenkrands I., Rasmussen, P.B., Carnio, M., Jacobsen, S., Theisen, M., **Andersen, P.**  
Identification and characterization of a 29 Kilodalton protein from *Mycobacterium tuberculosis* culture filtrate recognized by mice during the recall of immunity. *Infect. Immun.* 66: 2728-2735, 1998.

172. Weldingh, K., Rosenkrands, I., Jacobsen, S., Rasmussen, P.B., Elhay, M., **Andersen, P.**  
Two-dimensional electrophoresis for analysis of *Mycobacterium tuberculosis* culture filtrate and purification and characterization of six novel proteins. *Infect. Immun.* 66: 3492-3500, 1998.

173. **Andersen, P.**  
Host responses and antigens involved in protective immunity to *Mycobacterium tuberculosis*. *Scand. J. Immunol.* 45: 115-131, 1997.

174. **Andersen, P.**  
Ny tuberkulosevaccine. *Praksis Sektoren* 22: 45, 1997

175. Elhay, J.M., **Andersen, P.**  
Immunological requirements for a subunit vaccine against tuberculosis. *Immunol. Cell Biol.* 75: 595-603, 1997

176. Lindblad, E. B., Elhay, M.J., de Silva, R., Appelberg, R., **Andersen, P.**  
Adjuvant modulation of immune responses to tuberculosis sub-unit vaccines.  
*Infect. Immun.* 65: 623-629, 1997.

177. Pollock, J., **Andersen, P.**  
The potential of the ESAT-6 antigen secreted by virulent mycobacteria for specific diagnosis of tuberculosis. *J. Infect. Dis.* 175: 1251-1254, 1997.

178. Pollock, J., **Andersen, P.**  
Predominant recognition of ESAT-6 in the first phase of infection with *Mycobacterium bovis* in cattle. *Infect. Immun.* 65: 2587-2592, 1997.

179. Ravn, P., Boesen, H., Pedersen, B.K. & **Andersen, P.**  
Human T cell responses induced by vaccination with *Mycobacterium bovis* Bacillus Calmette-Guérin. *J. Immunol.* 158: 1949-1955, 1997.

180. Ravn, P., Boesen, H., Wilcke, T.J.R., **Andersen, P.**  
Secreted antigens and immune responses to *Mycobacterium tuberculosis*. *Medical Principles and Practice.* 6: 74-83, 1997.

181. **Andersen, P.**  
Purification of Proteins from *Mycobacterium tuberculosis* by Simultaneous Electro-Elution of the Mini Whole Gel Eluter. *Bio Rad, US/EG Bulletin* 2043, 1997.

182. **Andersen, P.**  
Immunity to *Mycobacterium tuberculosis*. Characterization of immune responses and antigens of relevance for immunity to tuberculosis. Dr.med. thesis, Copenhagen University 1996.

183. Brandt, L., Oettinger, T., Holm, A. & **Andersen, P.**  
Key epitopes on the secreted ESAT-6 antigen recognized in mice during the recall of protective immunity to *Mycobacterium tuberculosis*. *J. Immunol.* 157: 3527-3533, 1996.

184. Harboe, M., **Andersen, P.**, Colston, M.J., Gicquel, B., Hermans, P.W.M., Ivanyi, J., Kaufmann, S.H.E.  
Report of the Expert Panel IX: Vaccines against tuberculosis. *Vaccine* 14: 701-716 1996.

185. Harboe, M., Oettinger, T., Wiker, H.G., Rosenkrands, I., **Andersen, P.**  
Evidence for occurrence of the ESAT-6 protein in *Mycobacterium tuberculosis* and virulent *Mycobacterium bovis* and for its absence in *Mycobacterium bovis* BCG. *Infect. Immun.* 64: 16-22, 1996.

186. **Andersen, P.** Andersen, Å.B., Sørensen, A.L., Nagai, S.  
Recall of longlived immunity to *Mycobacterium tuberculosis* infection in mice. *J. Immunol.* 154: 3359-3372, 1995.

187. Boesen, H., Jensen, B.N., Wilcke, T., **Andersen, P.**  
Human T-cell responses to secreted antigens fractions of *Mycobacterium tuberculosis*. *Infect. Immun.* 63: 1491-1497, 1995.

188. Hasløv, K., Andersen, Å.B., Nagai, S., Gottschau, A., Sørensen, T., **Andersen, P.**  
Guinea pig immune response to proteins secreted by *Mycobacterium tuberculosis*. *Infect. Immun.* 63: 1498-1502, 1995.

189. Sørensen, A.L., Nagai, S., Houen, G., **Andersen, P.**, Andersen, Å.B. Purification and characterization of a low mass T cell antigen secreted by *Mycobacterium tuberculosis*. *Infect. Immun.* 63: 1710-1717, 1995.

190. **Andersen, P.** Effective vaccination of mice against *Mycobacterium tuberculosis* infection with a soluble mixture of secreted mycobacterial proteins. *Infect. Immun.* 62: 2536-2544, 1994.

191. **Andersen, P.** The T-cell response to secreted antigens of *Mycobacterium tuberculosis*. *Immunobiol.* 191: 537-547, 1994.

192. **Andersen, P.**, & Heron, I. Specificity of a protective memory immune response against *M. tuberculosis*. *Infect. Immun.* 61: 844-851, 1993.

193. **Andersen, P.**, Heron, I. Simultaneous electroelution of whole SDS-polyacrylamide gels for the direct cellular analysis of complex protein mixtures. *J. Immunol. Methods* 161: 29-39, 1993.

194. Orme, I.M., **Andersen, P.** & Boom, W.H. The T cell response to *Mycobacterium tuberculosis*. *J. Infect. Dis.* 167: 1481-1497, 1993.

195. Andersen, Å.B., **Andersen, P.** & Ljungquist, L. Structure, function of a 40,000-molecular-weight protein antigen of *Mycobacterium tuberculosis*. *Infect. Immun.* 60: 2317-2323, 1992.

196. **Andersen, P.**, Askgaard, D., Gottschau, A., Bennedsen, J., Nagai, S. & Heron I. Identification of immunodominant antigens secreted by *Mycobacterium tuberculosis*. *Scand. J. Immunol.* 36: 823-831, 1992.

197. **Andersen, P.**, Ljungquist, L., Hasløv, K., Bentzon, M.W. & Heron I. Proliferative response to seven affinity purified mycobacterial antigens in eight strains of inbred mice. *Intern. J. Leprosy.* 59: 58-67, 1991.

198. **Andersen, P.**, Askgaard, D., Ljungquist L., Bentzon, M.W. & Heron, I. T-Cell proliferative response to antigens secreted by *Mycobacterium tuberculosis*. *Infect. Immun.* 59: 1558-1563, 1991.

199. **Andersen, P.**, Askgaard, D., Ljungquist, L. Bennedsen, J. & Heron, I. Proteins released from *Mycobacterium tuberculosis* during Growth. *Infect. Immun.* 59: 1905-1910, 1991.

200. Ljungqvist, L., Andersen, Å.B., **Andersen, P.**, Hasløv, K., Worsaae, A., Bennedsen, J. & Heron, I. Affinity purification, biological characterization and serological evaluation of defined antigens from *Mycobacterium tuberculosis*. *Trop. Med. Parasitol.* 41: 333-335, 1990.